# EXHIBIT P

Exponent®

*Polymer Science and Materials Chemistry*

# Expert Report of Dr. Steven MacLean

**In the U.S. District Court for the Southern District of West Virginia, Charleston Division**

**This document relates to:**

***Pelvic Mesh Litigation***

**In re: Ethicon Inc., Pelvic Repair System Products Liability Litigation**
**MDL 2327**

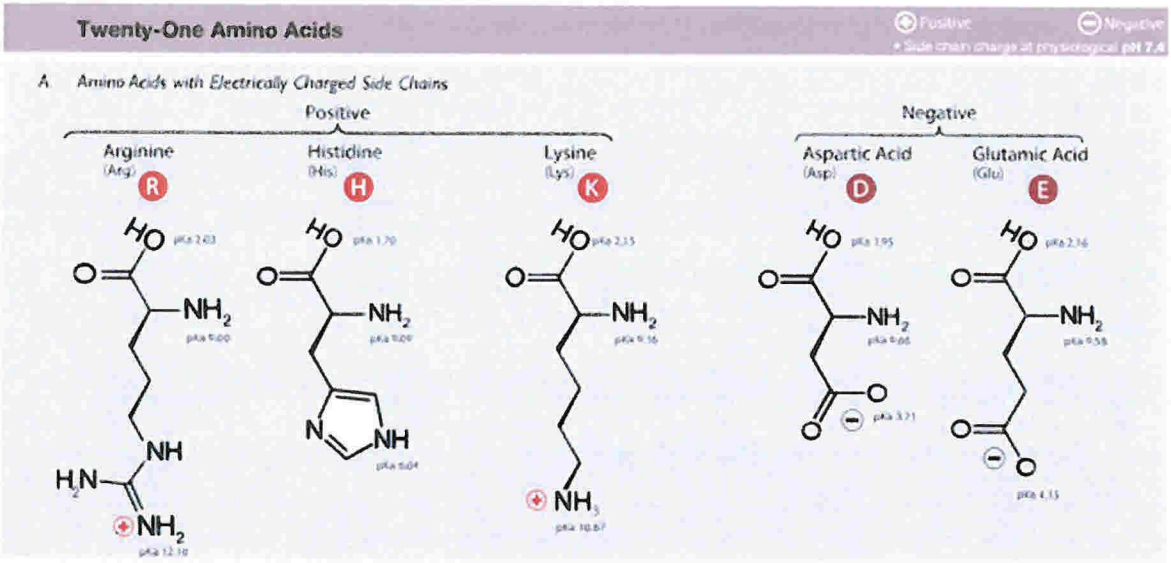


Figure 9. Amino acids that contain a net positive or negative charge.

## Experimental Investigation of the Capacity of PROLENE and Oxidized PROLENE to Accept H&E Stain

In addition to my reliance on the literature and first principles of polymer science, in order to further validate my assertion that H&E is not expected to stain PROLENE or oxidized PROLENE, Exponent conducted a set of laboratory experiments that serve as the control experiments Dr. Iakovlev failed to perform in his expert report. The details of these experiments are provided below.

### Sample Preparation Prior to Sectioning

#### Exemplar PROLENE Mesh

Pristine PROLENE mesh (Ref. No. 810041B, Lot No. 3661669) was received and kept in its original packaging until use. A clean razor blade was used to cut sections for laboratory analysis.

#### Chemically Oxidized PROLENE Mesh

Six sections of PROLENE mesh were oxidized according to the protocol published by Guelcher and Dunn.[63] Samples were incubated at 37°C for up to 5 weeks in oxidative media composed of 0.1 M $CoCl_2$ in 20 wt% $H_2O_2$. This solution purportedly simulates the oxidative environment

created by macrophages in response to a foreign object.[63] The oxidative solution was changed every 2-3 days. Prior to processing, the samples were copiously rinsed in de-ionized water, air-dried, and assessed for morphological changes using scanning electron microscopy (SEM).

#### QUV Oxidized PROLENE Mesh

Six sections of PROLENE mesh were placed inside a Q-Lab QUV Accelerated Weathering Tester and irradiated with 0.98 $(\frac{W}{m^2})$ UV-A and UV-B at 60°C for 5 days. As with the chemically oxidized meshes, the samples were assessed for morphological changes using SEM prior to processing.

### Sample Mounting and Sectioning

Exemplar and oxidized mesh samples were embedded in both paraffin and resin (Technovit), sectioned, and stained with Hematoxylin & Eosin. All processing was performed by an independent histology lab and observed by Exponent. Detailed embedding and staining protocols can be found in Appendix A.

Paraffin-embedded samples were prepared by following the protocol submitted by Dr. Iakovlev. Briefly, samples were sequentially dehydrated in reagent alcohol and Xylene substitute using an automated tissue processor, then embedded in Leica EM400 Paraffin wax. Sections of the paraffin blocks (4-6 µm thick) were obtained using a microtome, briefly floated in a 40-45°C water bath, then mounted onto slides. Sections were air-dried for 30 minutes then baked in a 45-50°C oven overnight.

Resin-embedded samples were sequentially dehydrated in reagent alcohol using an automated tissue processor, then embedded in Technovit 7200. The polymerized resin block was trimmed, cut, and ground to a thickness of approximately 50 µm.

Paraffin and resin-embedded samples were stained with Aqueous Eosin and Harris Hematoxylin using an automated stainer. All slides were imaged by Exponent personnel using a microscope equipped with polarizing filters.

## Results

### SEM on Oxidized Meshes

When viewed under a Scanning Electron Microscope (SEM), the QUV-oxidized mesh exhibited external cracking (Figure 10), while the chemically-oxidized mesh did not (Figure 11). This differs from the results published by Guelcher and Dunn, who reported "pitting" and "flaking" in polypropylene meshes subjected to the same treatment conditions.[63]

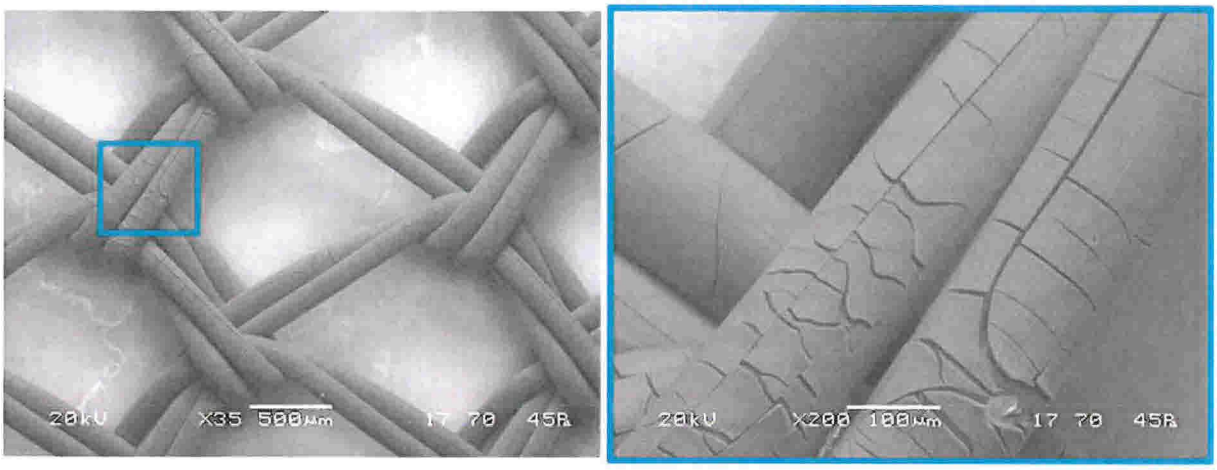


Figure 10. Scanning Electron Microscope images of QUV oxidized mesh.

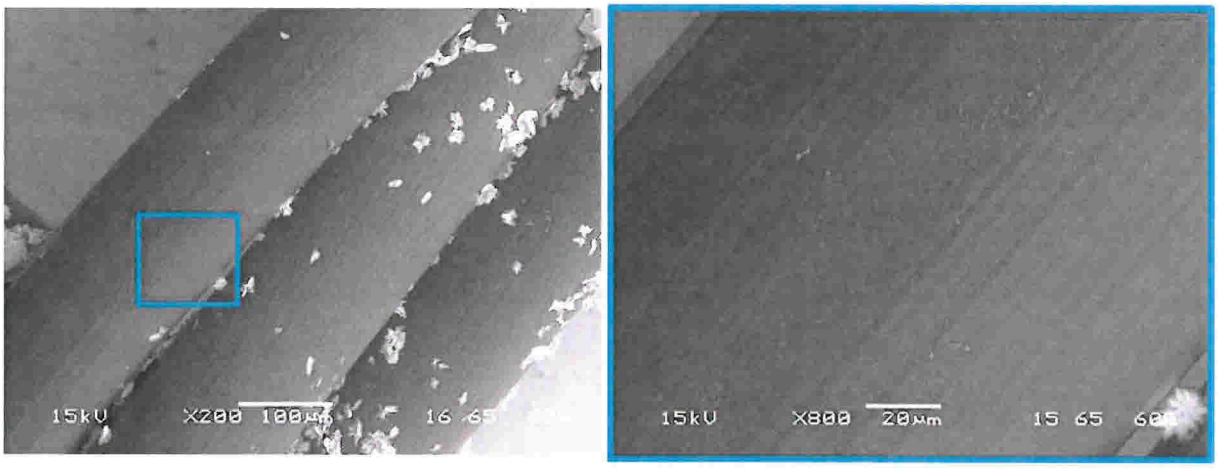


Figure 11. Scanning Electron Microscope images of mesh that was chemically-oxidized according to the Guelcher protocol.

- Dr. Iakovlev has not performed any control experiments nor cited any scientific studies that support his belief that degraded PROLENE is capable of being histologically stained with H&E stains, and for these reasons, his conclusions are flawed and suspect.

- Through a series of controlled oxidation, microtoming, and microscopy experiments, Exponent demonstrated that oxidized PROLENE meshes do not become stained with H&E dyes. This fact is supported by polymer science first principles, given that PROLENE does not possess chemical groups amenable to binding with the H&E stain molecules.

- Artifacts can be easily introduced during sample preparation, sectioning, staining, and imaging, giving the appearance of darkened outer layers.

- A brittle outer layer will not contribute to the stiffness of the mesh if it is thin, cracked, and discontinuous. Dr. Iakovlev's opinion that a thin, cracked, porous outer layer causes an increase in mesh stiffness is not consistent with first principles of polymer science and solid mechanics.

If you have any questions or require additional information, please do not hesitate to contact me.

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